

ACADEMIC RESEARCH ENHANCEMENT AWARD

RELEASE DATE: January 9, 2003

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APPLICATION RECEIPT DATES: January 25, May 25, September 25

AIDS-RELATED APPLICATION RECEIPT DATES: May 1, September 1, January 2

EXPIRATION DATE: This PA expires on January 2006, unless reissued.

National Institute on Aging (NIA)

(<http://www.nia.nih.gov/>)

National Institute on Alcohol Abuse and Alcoholism (NIAAA)

(<http://www.niaaa.nih.gov/>)

National Institute of Allergy and Infectious Diseases (NIAID)

(<http://www.niaid.nih.gov/>)

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

(<http://www.niams.nih.gov/>)

National Institute of Biomedical Imaging and Bioengineering (NIBIB)

(<http://www.nibib.nih.gov/>)

National Cancer Institute (NCI)

(<http://www.nci.nih.gov/>)

National Institute of Child Health and Human Development (NICHD)

(<http://www.nichd.nih.gov/>)

National Center for Complementary and Alternative Medicine (NCCAM)

(<http://www.nccam.nih.gov/>)

National Institute on Deafness and Other Communication Disorders (NIDCD)

(<http://www.nidcd.nih.gov/>)

National Institute of Dental and Craniofacial Research (NIDCR)

(<http://www.nidcr.nih.gov/>)

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

(<http://www.niddk.nih.gov/>)

National Institute on Drug Abuse (NIDA)

(<http://www.nida.nih.gov/>)

National Institute of Environmental Health Sciences (NIEHS)

[\(http://www.niehs.nih.gov/\)](http://www.niehs.nih.gov/)

National Eye Institute (NEI)

[\(http://www.nei.nih.gov/\)](http://www.nei.nih.gov/)

National Institute of General Medical Sciences (NIGMS)

[\(http://www.nigms.nih.gov/\)](http://www.nigms.nih.gov/)

National Heart, Lung, and Blood Institute (NHLBI)

[\(http://www.nhlbi.nih.gov/\)](http://www.nhlbi.nih.gov/)

National Human Genome Research Institute (NHGRI)

[\(http://www.nhgri.nih.gov/\)](http://www.nhgri.nih.gov/)

National Institute of Mental Health (NIMH)

[\(http://www.nimh.nih.gov/\)](http://www.nimh.nih.gov/)

National Institute of Neurological Disorders and Stroke (NINDS)

[\(http://www.ninds.nih.gov/\)](http://www.ninds.nih.gov/)

National Institute of Nursing Research (NINR)

[\(http://www.nih.gov/ninr/\)](http://www.nih.gov/ninr/)

National Library of Medicine (NLM)

[\(http://www.nlm.nih.gov/\)](http://www.nlm.nih.gov/)

National Center for Research Resources (NCRR)

[\(http://www.ncrr.nih.gov/\)](http://www.ncrr.nih.gov/)

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PURPOSE OF THIS PA

The National Institutes of Health (NIH) is continuing to make a special effort to stimulate research in educational institutions that provide baccalaureate or advanced training for a significant number of the Nation's research scientists but that have not been major recipients of NIH support. Since Fiscal Year (FY) 1985, Congressional appropriations for the NIH have included funds for this initiative, which NIH has implemented through the Academic Research Enhancement Award (AREA) program. Based on the expectation that funds will continue to be available each year, the NIH invites applications for AREA grants (R15) through a standing, an ongoing Program Announcement (PA).

AREA funds are intended to support new ("type 1") and continuing ("renewal" or "competing continuation" or "type 2") health-related research projects proposed by faculty members of eligible schools and components of domestic institutions. The AREA will enable qualified scientists to receive support for small-scale research projects. These grants are intended to create a research opportunity for scientists and institutions otherwise unlikely to participate extensively in NIH programs to support the Nation's biomedical and behavioral research effort. It is anticipated that investigators supported under the AREA program will benefit from the opportunity to conduct independent research; that the grantee institution will benefit from a research environment strengthened through AREA grants and furthered by participation in the diverse extramural programs of the NIH; and that students will benefit from exposure to and participation in research and be encouraged to pursue graduate studies in the health sciences.

ELIGIBILITY REQUIREMENTS

Applicant Schools/Components:

All health professional schools/colleges and other academic components of domestic institutions offering baccalaureate or advanced degrees in the sciences related to health are eligible, except those that have received research grants and/or cooperative agreements from the NIH totaling more than \$3 million per year (in both direct and indirect costs) in each of four or more of the last seven years. Note that this criterion of financial eligibility is based on the amount of NIH research grant monies received, not by the institution (university or college) as a whole, but by the individual school/college or aggregation of "other academic components" (see definition below) where the principal investigator has an appointment (e.g., School of Medicine, College of Nursing, etc.). To determine the eligibility of a school or component with regard to this requirement, applicants should consult the list of Ineligible schools/components on the AREA Web page at

<http://grants.nih.gov/grants/funding/area.htm>. If the name of the school does not appear on the list, it may be eligible to apply for AREA grants. Applicants should check with their own institutions if unsure.

For purposes of eligibility for the AREA program, the following definitions apply:

- o "Health professional schools" (schools or colleges of medicine, dentistry, osteopathy, pharmacy, nursing, veterinary medicine, public health, optometry, allied health, chiropractic, naturopathy and podiatry) means an accredited public or non-profit private school that provides training leading to a degree granted by that school (e.g., M.D., D.D.S., M.P.T., D.C., N.D. or equivalent degree). The term "accredited" means a school or program that is accredited by a recognized body or bodies approved for such purpose by the Secretary of Education.
- o "Research grants and cooperative agreements" includes all extramural awards designated by an activity code starting with R, P, M, S, K, or U, and also G12 and D42. Scientific evaluation awards (R09, U09) are excluded.
- o "Other academic components" means all schools, departments, colleges, and free-standing institutes of the institution EXCEPT the health professional schools, taken as a SINGLE component.

An applicant school/component may submit several applications proposing different research projects from different investigators.

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH programs.

- o May not be the principal investigator of any active NIH research grant at the time of award of an AREA grant (although he or she may be one of the project personnel for an active NIH grant held by another principal investigator).
- o May not be awarded more than one AREA grant at a time (although he or she may hold successive AREA grants).

- o May not submit an application to NIH for another research project grant for essentially the same project proposed in a pending AREA application (in accordance with the general NIH prohibition against the submission in the same review cycle of more than one application for the same work).
- o Is expected to conduct the majority of the research at the grantee institution, although limited use of special facilities or equipment at another institution is permitted.

Scientists working in AREA-eligible minority or women's educational institutions are encouraged to participate in this program.

MECHANISM OF SUPPORT

The R15 mechanism is used to designate applications and awards for AREA grants, to distinguish the special objectives of these grants from those of other types of NIH research grants. This award will enable scientists at eligible institutions to receive support for small research projects, which might include, feasibility studies, pilot studies, and other small-scale research programs. Through this mechanism, a maximum of \$150,000 in direct costs plus facilities and administrative (formerly, indirect) costs at the rate negotiated for the institution may be awarded for a period of up to three years. Allowable direct costs include salaries for the principal investigator and other research personnel (including students), supplies, equipment, travel, and other items specifically associated with the proposed research project.

Supplemental Funding of Existing Grants

For Underrepresented Minority Students: The NIH recognizes the need to increase the number of underrepresented minority scientists participating in biomedical and behavioral research. Therefore, it is emphasizing the use of administrative supplements to existing grants in order to attract underrepresented minorities into biomedical and behavioral research. Principal investigators at domestic institutions who hold an active NIH research grant (including an active AREA grant) are eligible to submit a request for an administrative supplement to the awarding component that issued the parent grant. For the purposes of an active AREA grant, the request will be to support a minority candidate who is a high school or undergraduate student. Exceptions to this rule may be made by the awarding component that issued the AREA grant. For a full discussion of this additional funding opportunity and procedures for submitting a request for a supplement, see the NIH Guide for Grants and Contracts, April 9, 2001 at the following Web site: <http://grants.nih.gov/grants/guide/pa-files/PA-01-079.html>

For Individuals with Disabilities: The NIH also recognizes the need to extend opportunities to individuals with disabilities who are capable of entering or resuming research careers. According to the Americans With Disabilities Act, a "disabled individual" is one who has a physical or mental impairment that substantially limits one or more major life activities, who has a record of such impairment, or who is regarded as having such an impairment.

Accordingly, principal investigators of an active AREA grant may also submit a request for an administrative supplement for this purpose to the awarding component that issued the parent grant. For a full discussion of this additional funding opportunity and procedures for submitting a request for a supplement, see the NIH Guide for Grants and Contracts, April 9, 2001 at the following Web site: <http://grants.nih.gov/grants/guide/pa-files/PA-01-080.html>

RESEARCH OBJECTIVES

Background

The NIH is the principal research arm of the Department of Health and Human Services (HHS). At present, 24 awarding components (known as Institutes or Centers) and several support and service Centers constitute the NIH. The NIH fosters the development of new knowledge in the biomedical and behavioral sciences, the ultimate goal of which is to combat disease and improve the health of mankind. To achieve its goals, the NIH conducts research in its own laboratories and clinics, and it funds research conducted in research and academic institutions throughout the world by means of grants, cooperative agreements, and contracts. The majority of grantees are academic institutions, but other organizations (including for-profit organizations) participate significantly in NIH-supported research. The NIH provides funds for research projects, research training, career development of new and established scientists, and research and medical library resources.

Research grants represent the largest proportion of all NIH extramural awards. The research plan for each research grant application is generated and developed by an investigator referred to as the "principal investigator." On behalf of the investigator, the institution submits the grant application to the NIH for consideration for support. Principal investigators of NIH grant applications are most frequently affiliated with universities or medical and dental schools, and most hold doctorate degrees. Requirements for who may be a principal investigator on an application (e.g., tenure-track status, citizenship status, etc.) are those of the institution, not NIH.

The NIH has long used a dual peer review system for the evaluation of applications. This system, which has a statutory base, ensures that only the most meritorious and relevant proposals are considered for funding. The first level of review involves panels composed primarily of non-Federal experts, referred to as Scientific Review Groups (SRGs) or "study sections" that are organized according to scientific areas. These panels of experts render an impartial review and evaluation of each application. They consider not only the scientific merit of a proposal, but also the background and experience of the principal investigator, the research facilities available for the project, and the appropriateness of the direct costs requested.

The second level of review is conducted by the National Advisory Council or Board of the awarding component to which the application is assigned. These groups, composed of scientists, physicians, dentists, and laypersons who are leaders in public affairs, are chosen for their expertise, interest, or activity related to the awarding component's mission. The council or board will take into account the relevance of the goals of the project in relation to the mission of the awarding component, program balance, and the availability of funds. The Center for Scientific Review (CSR), a component of the NIH, receives all grant applications submitted to the NIH, assesses each one for relevance to the health mission of the NIH; and assigns those that are acceptable to the appropriate Scientific Review Group (SRG) for initial scientific merit review, and to the appropriate NIH awarding component for consideration for an award.

The AREA program and its application, review, and award procedures have been developed within this established framework for NIH grant-supported research activities.

Research Objectives of the NIH Institutes and Centers

AREA grants will support small-scale, new or ongoing health-related meritorious research projects, including pilot research projects and feasibility studies; development, testing, and refinement of research techniques; secondary analysis of available data sets; and similar discrete research projects that demonstrate research capability. Listed below, by Institute or Center, are the research topics of particular interest to the Institute/Center under the AREA program. Listed in the INQUIRIES section is the AREA program representative for each of the participating Institutes and Centers. A potential applicant is encouraged to contact the person listed for the particular Institute(s) or Center(s) with research interests relevant to the applicant's proposed topic for additional scientific program information and for pre-application guidance.

The research objectives of the AREA program are those of the individual NIH Institutes and Centers, as follows:

National Institute on Aging (NIA or AG)

The NIA is interested in, and has responsibilities for, aging research that includes fundamental studies of biological processes, including studies of aging at the molecular, genetic, organelle, cellular, organ, and organ system levels; the interaction of aging and diseases of aging; biomedical and psychosocial factors in maintaining health and effective functioning in the middle and later years, relevant social and behavioral relationships; and research that broadens the base of knowledge underlying adequate health services for the aging and the aged. The Institute is interested in normal physiological and biochemical changes with aging, involving areas such as immunology, cognition, neurobiology, endocrinology, nutrition, and exercise physiology, as well as clinical diseases and disorders of aging such as Alzheimer's disease, impaired sleep, sensory and motor disorders, osteoporosis, osteoarthritis, falls, and urinary incontinence. The Institute also has responsibility for research concerned with the biological, social, psychological, cultural, epidemiological, demographic and economic factors that affect both the process of growing old and the status and roles of older people in society. Under this broad mandate, health and wellbeing are viewed as the outcome of complex biological, physiological, medical, psychological, and socioenvironmental processes.

National Institute on Alcohol Abuse and Alcoholism (NIAAA or AA)

The NIAAA supports basic and clinical research to develop new knowledge in a wide range of areas relevant to alcohol abuse problems and alcohol addiction. Areas of research include molecular, physiological, and behavioral mechanisms leading to pathological drinking behavior and alcohol-induced organ damage; identification of genes and gene-environment interactions that contribute to susceptibility; health services and outcomes research; and clinical, behavioral, and epidemiological studies that will lead to more effective diagnosis, prevention, and treatment of alcohol use disorders and associated alcohol-related medical conditions. Basic and clinical research on fetal alcohol spectrum disorders is also supported. The NIAAA encourages alcohol-relevant research in any of the basic science disciplines, epidemiology, social and behavioral sciences, computer modeling, and health economics.

National Institute of Allergy and Infectious Diseases (NIAID or AI)

The objective of NIAID's research program is to acquire the knowledge which will eventually lead to the treatment and prevention of infectious, allergic, and immunologic diseases. The Institute's overall strategy of attacking the array of problems on a broad front relies on free-ranging research in microbiology and includes the following research problem areas: isolation, characterization,

and biology of disease-causing microbes; antibiotic or drug resistance among bacteria, viruses, and parasites; development of successful and safe antimicrobial compounds, particularly for viruses and parasites; and new approaches to understand and manipulate the immune system.

National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS or AM)

The NIAMS supports basic and clinical studies related to the rheumatic diseases and to diseases and disorders of connective tissue, bone, and skin. Areas of research include: inflammation, infectious agents and genetic factors related to rheumatic diseases; structure and function of cartilage and connective tissue; arthritis in children; systemic lupus erythematosus; rheumatoid arthritis; - osteoarthritis; spondylitis and related syndromes; gout and pseudogout; the structure and function of skeletal muscle; bone structure, formation, degradation and repair; osteoporosis; biomaterials, biomechanics, and joint replacement; inherited connective tissue diseases; bone immunology and transplantation; metabolism of epidermis, dermis and subcutaneous fat; immunologically mediated cutaneous disorders; photobiology, photoallergy, and phototoxic reactions; vitiligo; psoriasis, bullous diseases of the skin; and acne.

National Institute of Biomedical Imaging and Bioengineering (NIBIB or EB)

The mission of the NIBIB is to improve health by promoting fundamental discoveries, design and development, and translation and assessment of technological capabilities in biomedical imaging and bioengineering, enabled by relevant areas of physics, chemistry, mathematics, materials science, information science, and the computer sciences. The Institute plans, conducts, fosters, and supports an integrated and coordinated program of research and research training that can be applied to a broad spectrum of biological processes, disorders and diseases, and organ systems. The Institute coordinates with the biomedical imaging and bioengineering programs of other agencies and NIH institutes to support imaging and engineering research with potential medical applications and facilitates the transfer of such technologies to medical applications. The Institute supports hypothesis-, design-, technology- or problem-driven research relating to the discovery, design, development, translation and assessment of new knowledge in biomedical imaging and bioengineering. This research may utilize, for example, an organ or disease as a model system for development purposes. The research should be assigned to another Institute or Center if it is primarily applicable to an organ, disease or mission of that entity. Alternatively, several Institutes or Centers may collaborate on research of mutual interest.

National Cancer Institute (NCI or CA)

The NCI is the Federal Government's principal agency for cancer research and control.

Programs of the NCI focus on: (1) cancer etiology including laboratory, field, and epidemiologic and biometric research on the cause and natural history of cancer and means for preventing cancer, as well as studies on the mechanisms of cancer induction and promotion by chemicals, viruses, and environmental agents; (2) cancer biology and diagnosis research in the areas of cell biology, immunology, molecular biology, developmental biology, biochemistry, genetics, and pathology; (3) cancer metastasis research in the areas of invasion, cell migration, progression and metastasis, and the studies focusing on tumor-host interactions; (4) cancer treatment research in the areas of drug development, biological response modifiers, and radiotherapy development, including diagnostic imaging and clinical trials for curing or controlling cancer; (5) early detection and diagnosis research, including studies of promising biomarkers; and (6) cancer prevention and control research, development, technology transfer, demonstration, and education and information dissemination programs to expedite the use of new information relevant to prevention, detection, and diagnosis of cancer and pretreatment evaluation, treatment, rehabilitation, and continuing care of cancer patients.

National Institute of Child Health and Human Development (NICHD or HD)

The goal of NICHD's research programs is the improvement of maternal, infant, and child health through support of basic and clinical research to elucidate normal and abnormal growth, development, and maturation, from gametogenesis through maturity. To this end, NICHD supports research in: reproductive biology, chemistry, and medicine; fertility regulation; contraceptive development and evaluation; perinatology, pregnancy, and labor; developmental and clinical genetics; developmental biology; developmental neurobiology; developmental and reproductive immunology; birth defects; population dynamics; developmental endocrinology; social, cognitive, and affective development; and the biological bases of behavioral development.

The NICHD also supports biomedical and behavioral research on mental retardation and developmental disabilities; pediatric, adolescent, and maternal HIV infection and AIDS; and, in the context of its National Center for Medical Rehabilitation Research, NICHD also supports the development of medical, behavioral, psychological, social, and technological interventions designed to optimize functioning after impairment, disability, or handicap.

National Center for Complementary and Alternative Medicine (NCCAM or AT)

The National Center for Complementary and Alternative Medicine (NCCAM) explores complementary and alternative healing practices in the context of rigorous science; it educates

and trains complementary and alternative medicine (CAM) researchers; and disseminates authoritative information to the public and professionals. CAM encompasses healthcare and medical practices that are not currently an integral part of conventional medicine. The list of CAM approaches evolves steadily as some are proven safe and effective and accepted within "mainstream" healthcare practices while others are rejected as being unsafe or ineffective. CAM practices are grouped within five major domains: (1) alternative medical systems (for example, Traditional Chinese Medicine, Ayurveda); (2) mind-body interventions, (for example, meditation, biofeedback); (3) biologically-based treatments (for example, herbal therapies, special diets); (4) manipulative and body-based methods (for example, chiropractic, massage); and (5) energy therapies (for example, Reiki, Qi gong). (Further examples of practices within each CAM domain can be viewed at <http://nccam.nih.gov/health/whatiscam/index.htm>)

In order to meet this mandate, NCCAM supports research and research training programs that increase our knowledge of basic mechanisms underlying CAM approaches, and of their safety and efficacy. Studies may range from basic, through translational, clinical, epidemiological and health services.

National Institute on Deafness and Other Communication Disorders (NIDCD or DC)

The NIDCD supports biomedical and behavioral research related to the normal and disordered processes of hearing, balance, smell, taste, voice, speech and language. Basic and clinical studies are encouraged of genetic, molecular, cellular, physiological, biochemical, and behavioral aspects of function in health and disease. The Institute also supports research concerned with disease prevention, health promotion and the special biomedical and behavioral problems associated with communication impairments and disorders.

National Institute of Dental and Craniofacial Research (NIDCR or DE)

The mission of the NIDCR is to promote the dental, oral and craniofacial health of the American people through the conduct and support of research and the training of researchers. This includes the support of basic, clinical, and behavioral research concerning the etiology, epidemiology, prevention, diagnosis, and treatment of dental, oral and craniofacial disorders and diseases. In this context, the NIDCR emphasizes research on caries and periodontal diseases; oral viral infections; oral aspects of AIDS/HIV infection; head and neck cancers; craniofacial development, physiology and malformations; orofacial pain and other oral sensory and motor dysfunctions; salivary glands and disorders such as Sjogren's Syndrome; temporomandibular joint disorders; and restoration and regeneration of dental, oral and craniofacial structures.

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK or DK)

The NIDDK supports a broad range of fundamental and clinical investigation related to numerous diseases affecting the public health, including diabetes; obesity; endocrinology and endocrine disorders including osteoporosis; kidney, urologic and blood diseases; and digestive and liver diseases and nutrition. These include genetic diseases such as cystic fibrosis, polycystic kidney disease and inborn errors of metabolism; autoimmune diseases such as type 1 diabetes and inflammatory bowel disease; and infectious diseases such as hepatitis and food borne illness.

National Institute on Drug Abuse (NIDA or DA)

The research programs of the NIDA are devoted to increasing the understanding of the causes, progression and consequences of drug abuse, as well as to developing effective prevention and treatments. Research is supported on the complex neurobiological, behavioral, clinical, social and environmental components of drug abuse and addiction. In addition, NIDA supports research on mechanisms, processes, and problems (e.g., studies of cognitive processes and general addictive processes) that may ultimately contribute to the understanding of drug abuse and addiction, although it does not involve examination of an abused drug or use of a drug-abusing sample. Studies of HIV/AIDS, HCV and other STDs and drug abuse are also of interest. Drugs studied in NIDA-supported projects include psychomotor stimulants (cocaine, methamphetamine), opiates/opioids, hallucinogens, designer drugs, marijuana/cannabinoids, nicotine and other tobacco components, inhalants, abused prescription drugs, and over-the-counter products. Research involves basic and clinical neurobiology, molecular and cellular biology, chemistry, pharmacology, genetics, immunology, epidemiology, medication development, behavioral treatment, and behavioral sciences, as well as disciplines in clinical research, social and community research, health services, and prevention interventions. NIDA also supports science education research projects.

National Institute of Environmental Health Sciences (NIEHS or ES)

Human health and human disease result from three interactive elements: environmental factors, genetic susceptibility, and age. The mission of the National Institute of Environmental Health Sciences (NIEHS) is to reduce the burden of human illness and dysfunction from environmental causes by further understanding each of these elements and how they interrelate. Environmental health comprises those aspects of human health, including quality of life, that are determined by physical, chemical, biological, social and psychosocial factors in the environment. Elements within the latter categories include socioeconomic status, education, and cultural variables, which can be considered as both individual and community-level influences. The Institute supports

research and training focused on identification, assessment, and mechanism of action of potentially harmful agents in the environment. Research results form the basis for preventative programs for environmentally-related diseases and for action by regulatory agencies. The NIEHS, thus, has responsibility for providing knowledge to assist in societal decisions related to the impact of physical and social exposures on human health. This responsibility mandates efforts toward a thorough understanding of the early manifestations and mechanisms of human disease due to exposure to hazardous environmental conditions, development of more accurate and rapid methods to predict and assess toxicity, enhancement of prevention and intervention strategies, and translation of research findings into information that can be used to improve public health.

National Eye Institute (NEI or EI)

The mission of the NEI is to gain new knowledge concerning the eye and visual system in health and disease. The NEI supports research and research training aimed at developing a more complete understanding of normal tissue and normal visual processes so that a more complete understanding may be gained of the abnormal processes that lead to diseases of the eye and disorders of vision. The major objectives of NEI-supported research are to discover the most appropriate and effective means to prevent, treat, and rehabilitate visual disorders, and to determine the best means to disseminate timely research findings and information that will promote visual health. Both basic and clinical research are funded under the following major NEI programs: Retinal Diseases; Corneal Diseases; Lens and Cataract; Glaucoma; Strabismus, Amblyopia, and Visual Processing; and Low Vision and Its Rehabilitation. Within each program, research ranges from attempts to elucidate the fundamental biological processes that underlie disease to the development and clinical testing of new diagnostic and therapeutic techniques.

National Institute of General Medical Sciences (NIGMS or GM)

The mission of the National Institute of General Medical Sciences is to support basic, biomedical research that contributes to fundamental cellular and physiological principles. General areas of interest include cell biology, biophysics, structural genomics, proteomics, bioinformatics, genetic mechanisms, developmental biology, chemistry, biochemistry, physiology, trauma and burn, anesthesiology, and pharmacology. The molecular, genetic, functional, and structural understanding of biological molecules, their interactions and their organization, as well as the discovery of approaches to their control will contribute to understanding mechanisms for a variety of diseases. NIGMS also supports research in the fields of mathematics, physics, computer science, and engineering that are applicable to its mission.

National Heart, Lung, and Blood Institute (NHLBI or HL)

The NHLBI supports basic and clinical research pertaining to the structure, function, and diseases of the cardiovascular system, lungs, blood and blood vessels, and sleep disorders. The Institute's also supports research in stem cell biology and transplantation, transfusion medicine, and blood resources. The NHLBI carries out its mission through a number of research programs that provide support for projects ranging from studies at the molecular level to whole body studies in man and animals. Examples of research areas supported by the Institute include atherosclerosis, hypertension, cerebrovascular disease (directed at the dependent variable of blood, heart, or blood vessel), coronary heart disease, peripheral vascular diseases, arrhythmias, heart failure, and shock, congenital and rheumatic heart diseases, cardiomyopathies and infections of the heart, circulatory assistance, lung cell and molecular biology, chronic obstructive lung diseases, pediatric pulmonary diseases, cystic fibrosis, sleep-disordered breathing, asthma, fibrotic and immunologic lung diseases, acute respiratory failure, pulmonary vascular diseases, HIV-associated lung disorders and bone marrow suppression, bleeding and clotting disorders, disorders of the red blood cell such as sickle cell disease and Cooley's anemia, bone marrow failure syndromes, and blood resources.

National Human Genome Research Institute (NHGRI or HG)

The NCHGR is currently engaged in a research program designed to characterize the human genome and the genomes of selected model organisms. This research program has the following interrelated goals: the construction of high resolution genetic linkage maps; the development of a variety of physical maps; the determination of the complete nucleotide sequence of the DNA of selected organisms; the development of the capability for collecting, storing, distributing, and analyzing the data produced; and the development of appropriate new technologies to achieve these goals. This project will develop a series of resources that will be available to the research community to facilitate both basic research and the application of the knowledge gained to the prevention, diagnosis, and therapy of disease.

National Institute of Mental Health (NIMH or MH)

The goal of the NIMH is to reduce the burden of mental and behavioral disorders through research on mind, brain, and behavior. To this end, the NIMH supports and conducts research into the fundamental processes of brain and behavior, translational studies linking basic neuroscience discoveries to mental disorders, intervention studies, and investigations to improve the delivery of mental health services in diverse settings. The NIMH is also committed to

supporting research to prevent the spread of HIV/AIDS and reduce the burden of illness in infected individuals through behavioral interventions, and to understand, prevent, and treat the consequences of HIV disease of the CNS.

National Institute of Neurological Disorders and Stroke (NINDS or NS)

The NINDS supports basic, translational and clinical research on healthy and diseased brains, spinal cord and peripheral nerves. Examples of specific research areas supported by NINDS include: development, neurotrophic factors, cognition, epilepsy, stroke, cerebrovascular disorders, neuropathic pain, traumatic brain and spinal cord injury, Parkinson's disease, Alzheimer's disease, Huntington's disease, multiple sclerosis, muscular dystrophy and other neuromuscular disorders, brain tumors, autism, and genetic disorders of the nervous system.

National Institute of Nursing Research (NINR or NR)

The mission of the National Institute of Nursing Research is to support clinical and basic research to establish a scientific basis for the care of individuals across the life span—from management of patients during illness and recovery to the reduction of risks for disease and disability, the promotion of healthy lifestyles, the improvement of quality of life in those with chronic illness, and care for individuals at the end of life. This research may also include families within a community context. According to its broad mandate, the Institute seeks to understand and ease the symptoms of acute and chronic illness, to prevent or delay the onset of disease or disability or slow its progression, to find effective approaches to achieving and sustaining good health, and to improve the clinical settings in which care is provided. Nursing research involves clinical care in a variety of settings including the community and home in addition to more traditional health care sites. The NINR's research extends to problems encountered by patients, families, and caregivers. It also focuses on the special needs of at-risk and under-served populations, with an emphasis on health disparities. In order to meet the mission of the NINR, AREA applicants are invited to submit applications related to 8 broad areas of research interest including: chronic illness experiences, cultural and ethnic considerations in health and illness, end of life/palliative care, health promotion and disease prevention, implications of genetic advances, quality of life and quality of care, symptom management of illness and treatment, and telehealth interventions and monitoring.

National Library of Medicine (NLM or LM)

The objective of NLM's research program is the support of investigations related to the generation, organization, and utilization of health knowledge. Such support may involve: (1) medical informatics research, a branch of investigation of the fundamental issues of health knowledge communication vis-a-vis advanced computer technologies; (2) research in health science librarianship and information science; or (3) assistance for the preparation and publication of scientific works in the health area.

National Center for Research Resources (NCRR or RR)

The NCRR administers programs that develop and ensure the availability of resources essential to the efficient and effective conduct of human health-related research. NCRR programs are primarily institutional in nature but, while support is generally in the form of resource grants, the NCRR makes awards for support of projects which contribute to improvement of the capability of resources to serve biomedical research. The following are research areas appropriate to the NCRR interests: (1) Research and Development in Instrumentation and Specialized Technologies for Biomedical Research. This encompasses instruments, devices, and processes to facilitate research in biomolecular and cellular structure and function. (Instrumentation includes mass spectrometry, nuclear magnetic resonance, electron spin resonance, equipment for fast kinetic research, X-ray diffraction, electron microscopy, and flow cytometry.) The application of computer science, computer engineering, and biomedical engineering to biomedical research problems is also of interest. (This includes knowledge engineering, information technology, computer graphics, image processing, computer modeling and simulation, task dedicated computer systems, and development of implantable microsensors and transducers.); (2) Research in Laboratory Animal Sciences. (This includes the etiology, pathogenesis, and control of laboratory animal diseases, as well as the environmental requirements of laboratory animals.); and (3) Development of Biomedical Research Methods Employing Lower Organisms, Tissues/Cells in Culture, or Mathematical and Computer Simulations.

APPLICATION PROCEDURES

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). The PHS 398 is available at <http://grants.nih.gov/grants/funding/phs398/phs398.html> in an interactive format. For further assistance contact GrantsInfo, telephone (301) 435-0714, email: GrantsInfo@nih.gov.

Applicants should use the PHS 398 with the AREA guidelines. See <http://grants.nih.gov/grants/funding/area.htm>. The PHS 398 contains instructions on submission

procedures that must be observed by AREA applicants. These instructions must be adhered to, except where they have been modified by the following Supplemental Instructions.

SUPPLEMENTAL INSTRUCTIONS

As AREA applications are one of the mechanisms included in NIH's Modular Grants initiative, applicants must observe the supplemental instructions for modular grant applications contained in the Notice published in the NIH Guide for Grants and Contracts on December 18, 1998 (<http://grants.nih.gov/grants/guide/notice-files/not98-178.html>). Briefly, the features of modular grants related to application preparation include: the requirement that direct costs be requested only in modules of \$25,000, the omission of information on detailed budget categories and on pending "Other Support," and the inclusion in the "Biographical Sketch" of information on related research projects in which key personnel are currently participating or have participated.

The specific instructions below refer to those items in the PHS 398 application form where the information requested, following from the Modular Grant initiative or the AREA program requirements, either has been modified or should not be provided at submission although the information may be requested after initial review by the NIH awarding component if there is a likelihood that the application will be funded.

PHS 398

o FACE PAGE:

Item 2 -- Check the "YES" box and enter "Academic Research Enhancement Award" as the title. The PA number should be entered.

Item 6 --The entire proposed project period must not exceed three years.

Items 7a and 7b should be completed, indicating Direct Costs (in \$25,000 increments up to a maximum of \$150,000) and Total Costs [Modular Total Direct plus Facilities and Administrative (F&A) costs] for the entire budget period. Items 8a and 8b, which are identical to Items 7a and 7b, respectively, in AREA applications, should be completed indicating the Direct and Total Costs for the entire proposed period of support. AREA grants are multiyear funded, therefore the requested budget period and total project period must be identical.

o DETAILED BUDGET FOR THE INITIAL BUDGET PERIOD - Do not complete Form Page 4 of the PHS 398. It is not required and will not be accepted with the application.

o BUDGET FOR THE ENTIRE PROPOSED PERIOD OF SUPPORT - Do not complete the categorical budget table on Form Page 5 of the PHS 398. It is not required and will not be accepted with the application.

o NARRATIVE BUDGET JUSTIFICATION - Prepare a Modular Grant Budget Narrative page. (See <http://grants.nih.gov/grants/funding/modular/modular.htm> for sample pages.) At the top of the page, enter the total direct costs requested for each year. This is not a Form page.

o Under Personnel, list all project personnel, including their names, percent of effort, and roles on the project. No individual salary information should be provided. However, the applicant should use the NIH appropriation language salary cap and, if appropriate, the NIH policy for graduate student compensation in developing the budget request.

o The students who will be involved in the research should be included here. If they have not yet been individually identified, the number and academic level of those to be involved should be provided. Since a primary objective of the AREA program is to support investigators doing meritorious research at non-research intensive and/or undergraduate institutions, principal investigators are encouraged to include students in the proposed research to the extent practicable.

- If there are any Consultants for the project, provide their names, organizational affiliations, and the services they will perform.

For Consortium/Contractual costs, provide an estimate of total costs (direct plus facilities and administrative) for each year, each rounded to the nearest \$1,000. List the individuals/organizations with whom consortium or contractual arrangements have been made, the percent effort of all personnel, and the role on the project. Indicate whether the collaborating institution is foreign or domestic. The total cost for a consortium/contractual arrangement is included in the overall requested modular direct cost amount, which is a maximum of \$150,000. Include the Letter of Intent to establish a consortium.

o BIOGRAPHICAL SKETCH - The Biographical Sketch provides information used by reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as

well as to evaluate the overall qualifications of the research team. A biographical sketch is required for all key personnel, including collaborators, following the instructions below. No more than four pages may be used for each person. A sample biographical sketch may be viewed at: <http://grants.nih.gov/grants/funding/modular/modular.htm>

- Complete the educational block at the top of the form page;
- List position(s) and any honors;
- Provide information, including overall goals and responsibilities, on research projects ongoing or completed during the last three years;
- List selected peer-reviewed publications, with full citations.

For the principal investigator only, provide information on his or her: (a) previous or current experience in supervising students in research, and/or (b) other relationships within the institutional framework (e.g., cross-departmental research collaborations).

OTHER SUPPORT

Do not submit this page. However, the Biographical Sketch for each of the key personnel should include information on the other projects that the person is working on or has worked on that are relevant to the proposed project (see above).

RESOURCES

In addition to the information requested on the Form, under "Other," provide the following information:

- o a profile of the students of the applicant school/academic component and any information or estimate of the number who have obtained the baccalaureate degree and gone on to obtain an academic or professional doctoral degree in the health-related sciences during the last five years;
- o a description of the special characteristics of the school/academic component that make it appropriate for an AREA award, where the goals of the AREA program are to: (1) strengthen the research environment of schools that are not research intensive; (2) expose students in such environments to research, and (3) provide support for meritorious research.
- o a description of the likely impact of an AREA award on the principal investigator and the school/academic component. How will the AREA award strengthen the research environment of the school/academic component? How will the AREA award expose students to research?

- o a statement of institutional support for the proposed research project (e.g., release time, other support, matching funds, etc.).
- o CHECKLIST - This page should be completed and submitted with the application. If the F&A rate agreement has been established, indicate the type of agreement and the date. All appropriate exclusions must be applied in the calculation of the F&A costs.
- o The applicant should provide the name and phone number of the individual to contact concerning fiscal and administrative issues if additional information is necessary following the initial review.

PERSONNEL REPORT

Do not submit this page. Instead, this information should be provided in the Narrative Budget Justification (see above).

REVIEW CONSIDERATIONS

AREA applications are reviewed by scientific review groups administered by the NIH Center for Scientific Review (CSR) and are evaluated for scientific and technical merit according to standard NIH peer review procedures, as described above (see Background). Applications will be assigned on the basis of established Public Health Service referral guidelines. As part of the initial merit review, a streamlined review process, which is employed for the review of most NIH research grant applications, may be used. Under this process, reviewers are asked to identify the upper half of applications. These applications are discussed at the review group meeting and receive a priority score ranging from "best" (100) to "average" (300), while the lower half of applications are normally not discussed nor given a priority score. Nevertheless, all applicants will receive a summary statement, which will consist of the written critiques of two or more of the reviewers participating in the review group meeting.

The review schedule that will apply to AREA grant applications is as follows:

	Cycle I	Cycle II	Cycle III
Postmark Dates for:			
- All Other AREA Applications:	Jan 25	May 25	Sep 25
- AIDS-Related Applications:	May 1	Sep 1	Jan 2
Scientific Merit Review:	Jun/Jul	Oct/Nov	Feb/Mar
Advisory Council Review:	Sep/Oct	Jan/Feb	May/Jun

Earliest Project Start Date: Dec April July

Review Criteria: In carrying out the scientific and technical merit review of AREA applications, the scientific review group will base its recommendation and score (if the application is scored) on the overall impact of the application on its field of study by considering the following review criteria:

(1) Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

(2) Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

(3) Innovation: Does the project employ novel concepts, approaches or method?
Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

(4) Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

(5) Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

Is the applicant school/academic component suitable for an award in terms of strengthening the research environment.

In addition, all applications will be evaluated with respect to the appropriateness of the budget, the inclusion of children, minorities, and women in clinical research projects, the procedures for the protection of animal or human subjects, and the adequacy of protections for research personnel from biohazards. Further information about these considerations is available at: <http://www.csr.nih.gov/guidelines/proc.htm>.

AWARD CRITERIA

AREA grants are awarded on a competitive basis. Funding decisions on individual applications will be based on the proposed research project's scientific merit as evaluated in the initial scientific merit review and its relevance to NIH programs, and on the applicant institution's contribution to the undergraduate preparation of doctoral-level health professionals. Thus, after the initial scientific-technical review, applications receive a second-level review by the National Advisory Council of the Institute or Center to which the application has been assigned for potential funding. In conformance with the spirit of the House Committee Report 98-911 (to accompany H.R. 6028, HHS Appropriations for FY 1985), special consideration will be given in the funding decision process to applications from those "smaller, less prominent, four-year, public and private colleges and universities which provide undergraduate training for a significant number of our nation's research scientists but which have not shared adequately in the growth of the NIH extramural program."

Both annual Progress Reports and a Final Progress Report will be required of all AREA grantees.

WHERE TO SEND INQUIRIES

We encourage your inquiries concerning this PA and welcome the opportunity to answer questions from potential applicants. For inquiries of a scientific nature, potential applicants should contact the Program Contact persons for the Institutes whose scientific interests most closely match those of the proposed research (see Research Objectives section above). The Program Contacts for the Institutes and Centers are:

National Institute on Aging

Dr. Miriam Kelty

Associate Director, Office of Extramural Affairs

7201 Wisconsin Avenue, Room 2C218

Bethesda, MD 20892-9205

Phone: (301) 496-9322

FAX: (301) 402-2945

E-mail: mk46u@nih.gov

National Institute on Alcohol Abuse and Alcoholism

Dr. Laurie Foudin

Division of Basic Research

6000 Executive Boulevard, Suite 402

Bethesda, MD 20892-7003

Phone: (301) 443-0912

Fax: (301) 594-0673

E-mail: lf29z@nih.gov

National Institute on Allergy and Infectious Diseases

Mr. Al Czarra

Director, Office of Program Coordination and Operations

Division of Extramural Activities

Solar Building, Room 3C28

Bethesda, MD 20892

Phone: (301) 496-7291

Fax: (301) 402-0369

E-mail: ac20a@nih.gov

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Dr. Steven J. Hausman

Deputy Director

Building 31, Room 4C32

Bethesda, MD 20892-2350

Phone: (301) 402-1691

Fax: (301) 480-6069

E-mail: sh4lg@nih.gov

National Institute of Biomedical Imaging and Bioengineering

Dr. Grace C. Y. Peng

Program Director

6707 Democracy Blvd., Room 226, MSC 5469

Bethesda, MD 20892-5469

Phone: (301) 496-9178

Fax: (301) 480-0679

E-mail: penggr@mail.nih.gov

National Cancer Institute

Dr. Florence J. Hoffmann Pedersen

NCI Referral Officer

6116 Executive Blvd., Suite 8041

Phone: (301) 496-3428 Fax: (301) 402-0275

E-mail: ncirefof@dea.nci.nih.gov

National Institute of Child Health and Human Development

Dr. Susan Streufert

Office of the Deputy Director

6100 Executive Blvd., Room 4A01

Bethesda, MD 20892-7510

Phone: (301) 435-6856

Fax: (301) 402-4083

E-mail: ss149n@nih.gov

National Center for Complementary and Alternative Medicine

Dr. Neal B. West

Program Officer

Two Democracy Plaza, Suite 401

Phone: (301) 402-5867

Fax: (301) 480-3621

E-mail: westn@mail.nih.gov

National Institute on Deafness and Other Communication Disorders

Barry J. Davis, Ph.D.

Scientific Programs Branch

Division of Extramural Research

EPS-400D MSC 7180

6120 Executive Blvd.

Rockville, MD 20892-7180

Phone: 301-402-3464

FAX: 301-402-6251

E-mail: Barry_Davis@nih.gov

National Institute of Dental and Craniofacial Research

Dr. Dennis F. Mangan

Referral Liaison

Building 45, Room 4AN-18

Bethesda, MD 20892-6402

Phone: (301) 594-2421

Fax: (301) 480-8319

E-mail: dennis.Mangan@nih.gov

National Institute of Diabetes and Digestive and Kidney Diseases

Dr. Robert Hammond

Director, Division of Extramural Activities

Two Democracy Plaza, Room 715

6707 Democracy Blvd.

Bethesda, MD 20892-5456

Phone: (301) 594-8834

Fax: (301) 480-4125

E-mail: rh247f@nih.gov

National Institute on Drug Abuse

Dr. Teresa Levitin

Director, Office of Extramural

6001 Executive Blvd., Room 3158

Bethesda, MD 20892-9547

Phone: (301) 443-2755

Fax: (301) 443-0538

E-mail: tl25u@nih.gov

National Institute of Environmental Health Sciences

Dr. Jerrold Heindel

P.O. Box 12233, North Campus MD 3-03

Research Triangle Park, NC 27709

Phone: (919) 541-0781

Fax: (919) 541-2843

E-mail: heindelj@niehs.nih.gov

National Eye Institute

Dr. Ralph J. Helmsen

Research Resources Officer

Executive Plaza South, Suite 350

Bethesda, MD 20892-7164

Phone: (301) 451-2020

Fax: (301) 402-0528

E-mail: rh27v@nih.gov

National Institute of General Medical Sciences

Dr. Jean Chin

Program Director

Building 45, Room 2AS.19A

Bethesda, MD 20892-6200

Phone: (301) 594-2485

Fax: (301) 480-2004

E-mail: chinj@nigms.nih.gov

National Heart, Lung, and Blood Institute

Dr. Helena O. Mishoe

Office of Minority Health Affairs

6701 Rockledge Drive, Room 6218

Bethesda, MD 20892-7913

Phone: (301) 451-5081

Fax: (301) 480-0862

E-mail: hm31y@nih.gov

National Human Genome Research Institute

Dr. Bettie J. Graham

Chief, Research Grants Branch

Building 38A, Room 610

Bethesda, MD 20894

Phone: (301) 496-7531

Fax: (301) 480-2770

E-mail: bg30t@nih.gov

National Institute of Mental Health

Dr. Jean G. Noronha

NIMH Referral Liaison

6001 Executive Boulevard, Room 6154 MSC 9609

Bethesda, MD 20892-9609

Telephone: (301) 443-3367

FAX: (301) 443-4720

E-mail: jnoronha@nih.gov

National Institute of Neurological Diseases and Stroke

Dr. Randall R. Stewart

NINDS AREA Grant Coordinator

Neuroscience Center, Room 2135

6001 Executive Boulevard

Bethesda, MD 20892-9523

Phone: (301) 496-6460

Fax: (301) 402-1501

E-mail: stewartr@ninds.nih.gov

National Institute of Nursing Research

Dr. Hilary Sigmon

Program Director

Office of Extramural Programs

One Democracy Plaza, Room 710

Bethesda, MD 20892-4870

Phone: (301) 594-5970

Fax: (301) 480-8260

E-mail: hilary.sigmon@nih.gov

National Library of Medicine

Dr. Milton Corn

Division of Extramural Programs

Building 38A, Room 5N505

Bethesda, MD 20894

Phone: (301) 496-4621

Fax: (301) 402-0421

E-mail: rd57e@nih.gov

National Center for Research Resources

Dr. Louise E. Ramm

Deputy Director

Building 12A, Room 4009

Bethesda, MD 20892-5662

Phone: (301) 496-6023

Fax: (301) 402-0006

E-mail: lr34m@nih.gov

Questions regarding eligibility, policies, procedures, and other administrative aspects of the NIH AREA program should be referred first to the Office of Sponsored Programs at the educational institution. Issues that remain after consultation with the institutional Office of Sponsored Programs and that are not addressed in these AREA Program Guidelines may be directed to:

Marie A. Willett
NIH AREA Coordinator
Office of Extramural Research
National Institutes of Health
6705 Rockledge Drive, Room 3536
Bethesda, MD 20892
Phone: (301) 435-2689
Fax: (301) 480-0146
E-mail: willettm@od.nih.gov

These Program Guidelines and other information related to the AREA program are available on the AREA Web page at: <http://grants.nih.gov/grants/funding/area.htm>

REQUIRED FEDERAL CITATIONS

MONITORING PLAN AND DATA SAFETY AND MONITORING BOARD: Research components involving Phase I and II clinical trials must include provisions for assessment of patient eligibility and status, rigorous data management, quality assurance, and auditing procedures. In addition, it is NIH policy that all clinical trials require data and safety monitoring, with the method and degree of monitoring being commensurate with the risks (NIH Policy for Data Safety and Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: <http://grants.nih.gov/grants/guide/notice-files/not98-084.html>).

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the AMENDMENT "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html>);

a complete copy of the updated Guidelines are available at

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS:

The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at <http://grants.nih.gov/grants/funding/children/children.htm>.

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS:

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT:

The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part

with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in a NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This PA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople>.

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance, No. 93.390. Awards are made under the authority of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158; 42 USC 241 and 285) and administered in accordance with the PHS Grants Policy Statement and Federal regulations at 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development

services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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Department of Health
and Human Services



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